UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,975	04/07/2004	Daniel Santi	020547-003700US	9532

20350 7590 12/11/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/820,975	**Applicant(s)** SANTI ET AL.	
	Examiner Ileana Popa	**Art Unit** 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-20*.
   Claim(s) withdrawn from consideration: *21-30*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: see continuation sheet.

Ileana Popa

AU1633

Continuation of 3. NOTE: The proposed amendments will not be entered because they introduce new issues that require additional search and consideration for relevant art.

Continuation of 13.

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Mandecki et al. (Gene, 1988, 68: 101-107).

Applicant argues that Mandecki et al. describe a method wherein individual fragments are clones into vectors, wherein the fragments are excised by restricition digestion, wherein the fragment are gel-purified and ligated together, wherein the resulting ligation product is gel-purified and then ligated to a similarly prepared second ligation product followed by restriction digestion, gel purification, and cloning inot a vector. Therefore, Applicant argues that the ligation products of Mandecki et al. are selected using gel electrophoresis and not based on a selectable marker. Applicant argues that the necessity for fragment isolation is cumbersome, slow, and expensive; by contrast, the instatn invention advantageously avoids gel purification. Applicant also argues that Mandecki et al. only describe identifying transformants using lacZ, i.e., they do not teach identifying selecting a ligation product based on a selectable marker. With respect to the limitation of "at elast three different vectors", Appicant argues that, although Mandecki et al. describe three different vectors, they are not used together in a coordianted fashion, or even in the same sybthesis, as are trhe vectors of theinstatn invention.

In response to Applicant's arguments, it ias noted that Mandecki et al. teach using four types of pUC-derived plasmid vectors, each comprising lacZ as a selectable marker and each vector containing a DNA insert; after cleaving, the inserts are simultaneously ligated an cloned in pUC-derived plasmid comprising lacZ (i.e., selection of the ligation product is based on a selectable marker present on one of the DNA vectors) (p. 103, columns 1, first full paragraph and paragraph bridging column 2, column 2, first full paragraph, p. 104, column 1, p. 106, legend of Fig. 4). Appliacnt's argument that the ligation products of Mandecki et al. are selected by gle electrophoresis and not by using a selectable marker is not found persuasive because the claims only require selecting the final ligation product based on a selectable marker of one of the three DNA vectors; this is exactly what Mandecki et al. disclose by selecting the trasformants; the rtransformants are selected based on the preseence of the finla ligation product that comprises lacZ, i.e., a selectable marker. Applicant's arguments that the method of Mandecki et al. requires gel purification and does not use coordthe new claims 31 and 32 recite a marker that is not taught by Mandecki et al., it is noted that the amnedments to the claims have not been entered, and therefore, Applicant's argument is directed to embodiments that are not in the claims. Therefore, Mandecki et al. teach all the claim limitations and the rejection is maintained.

Claims 1-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lebedenko et al. (Nucleic Acids Research, 1991, 19: 6757-6761), in view of both Gokhale et al. (Science, 1999, 284: 482485) and Slater et al. (PGPUB 2005/0074883).

Applicant argues that the Examiner fails to suggest any reason why one of skil in the art would modify Lebedenko et al. to add a selectble marker and a counter-selectable marker and that the Examiner did not provide any indication as to why one of skill in the art woild know how to accomplish what Applicant has invented. With respect to the Type 1, 2, and 3 molecules, Applicant argues that the specification dislcoses that these molecules differe by other factors, not only by the selectable markers (paragraphs 0231-0235, and the Figures). Finally, Applicant argues that the Examiner did not provide any basis for the rejection of claims 14-20.

In response to Appliant's arguments, it is noted that the limitation of directed ligation by using DNA having a selectable and a counter-selectable marker is taught by the prior art (see Slater et al., paragraph 0013, 0063, 0094, 0125, 0131). Based on these teachings, one of skill in the art would know to use selectable and counter-selectable markers for the selection of the desired ligation product. With respect to the Type 1, 2, and 3 vectors, the paragraphs indicated by the Applicant and the Figures fail to aupport the argument that these molecules differ by more htan the selctable markers. It is noted that, the specification clearly teaches that the Type 1, 2, and 3 molecules are diffrerent in respect to their selectable and counter-selectable markers (see paragraphs 0015, 0053, and 0230); there is no indication of any other difference in the specficiation. With respect to the argument that one of skul in the art would not have been expected to have a reasonable expectation of success in using more than one molecule (i.e., assembling larger gene) is just an argument not supported by any evidence and it is not found persuasive. The prior art clearly teaches that such mehtods can be used to assembly genes (see also Mandecki et al.); Applicant did not provide any evidence to the contrary. With respect to the argument the Examiner did not provide any basis for rejecting claims 14-20, Applicant is invited to carefully read the non-final Office action of 04/19/2006, describing the rejection of theembodiments recited in claims 14-20. Therefore, the rejection is maintained.